

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

"WHAT YOU NEED TO KNOW TO ENSURE COMPLIANCE WITH
THE NEW FDA BIOTERRORISM ACT REGISTRATION AND PRIOR
NOTICE INTERIM FINAL RULES"

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P R O C E E D I N G S

MR. : (in progress) I believe is what he is saying. Wine is produced at a winery. It is shipped in bulk to a bottler. The question is does the winery have to register and/or does the bottler have to register. In this case, both would be required to register. That's the short answer.

There are many permutations on that question that we have been asked so far. There are wineries that produce wine that is never intentionally shipped to the U.S. It is sent to a negociant or to others that will handle it and bottle it, put on different labels. It would not be the winery label. And there is many different transshipments, and some of that product may end up into the United States.

That is a little bit less clear as to whether the winery needs to register. But generally speaking, if the winery is manufacturing or processing a food such as wine, it should register if that product is consumed in the U.S.

MR. : I may not -- since I haven't used the microphone, what is the cork of a bottle considered?

MR. : It is a food contact substance and a cork is considered a food contact substance, and the manufacturer of cork is excluded from this rule. It's similar to a bottle, similar to a container, similar to a package.

MR. : Thank you.

MR. : Yes, sir.

MR. : I've got a question about nitrogen packaging gases. We are a gas manufacturer, MG Industries. If nitrogen is used in a variety of foods as a cover gas, is that covered by this registration? Are nitrogen manufacturers needing to register?

MR. : The question is, is nitrogen that's used in the manufacture of certain foods as an atmosphere in packaging, is that considered covered by this rule? The answer is yes. Gases or other food additives that are approved as food grade are considered foods, and they are not excluded from the definition of food, and therefore are covered.

The problem that we have been apprised of is there are many chemicals or gases that are produced that are not always used for food production. There are many.

So the question is if you know that your product is being used for food production, it's produced here in the U.S., then it is -- you are required to register. Obviously if you produce a product but you do not know what its final intent is, then it's a gray area. But generally speaking, if you are producing food-grade products such as that, that are food additives, you are required to register.

MR. : Is it also necessary to register a site if it's already registered as a drug manufacturer with the FDA?

MR. : The answer is yes, you need to register as a food facility. Being registered either as a low-acid canned food facility or -- I mean any other registration to any other department of FDA or to other Federal agencies does not satisfy this rule. You still must register even if you are registered under other registrations.

MR. : All right, as a last question, would it also cover liquid nitrogen used for freezing of food? Would that manufacturer of the liquid nitrogen --

MR. : Does the liquid nitrogen come in contact with the food?

MR. : It would be the freezing agent
for the food.

MR. : Does it come in contact with
the food?

MR. : But it's not in the final
product.

MR. : Okay. The answer is liquid
nitrogen is similar to refrigerants, and refrigerants don't
come in contact with the food, it's simply a refrigerator.
So my question is, if liquid nitrogen comes in contact with
the food, then it qualifies as a food additive.

MR. : Okay.

MR. : If it doesn't, if it is simply
used in a container, that encompasses the food, then it is
not.

MR. : Okay, I think you answered -- I
think you might have answered the question that I have, but
I'll ask it, anyway, just to make sure.

We import a five-liter container into which we
put a beverage, and it comes from Germany and it's purged
with nitrogen in Germany before it is shipped. The
question is do I have to submit a prior notice for bringing

those containers into the country since the product that we're putting in the container does come in contact with that nitrogen?

MR. : Okay, you've jumped to the next presentation, but I will -- for subsequent questioners, if you would please state your name and who you are with, but I will answer your question so you don't go away somewhat dissatisfied.

The answer is food contact substances have been excluded from the definition of food in both registrations, and a barrel is considered a food contact substance, and therefore is not covered either by prior notice or by registration.

MR. : Thank you.

MR. : Jay Ansell, Yves Roche. I have a question concerning the definition of retailer. We have a mail order business, a large warehouse which packages packages, small packages which go directly to the consumer. Does that make the warehouse a retail establishment?

MR. : Does -- okay, the question is, is the warehouse a retail establishment. If the

warehouse's annual sales exceed 50 percent of sales directly to consumers, the answer is yes.

MR. : Thank you.

MS. : Hi. My name is Donna Malloy. I'm with the USDA. I was wondering, your exemption for farms, does that include feedlots?

MR. : The question is does it include feedlots. The answer is yes.

MS. : Okay. Thank you.

MR. : My name is Rob Deford. I own Bordie Vineyards (phon.), which is a local winery, and I'm curious about how you come up with the 50 percent rule. Is it by volume or by revenues? And secondly, if the winery brings fruit in from out of the country, yet sells more than half its product retail, do we need to register? So two questions for you.

MR. : Okay, retail. The retail definition is 50 percent fiscal year or annual year sales.

MR. : Okay. All right. And then if we import fruit from out of the country, it's incorporated into a wine, let's say grapes are incorporated into a wine, yet that wine is sold retail, do we need to register?

MR. : Well, I've already answered your question. If you are a retailer and your sales are 50 percent or more, you are excluded.

MR. : Okay. Irrespective of the origin of the ingredient?

MR. : Right. The definition of retailer is your sales are 50 percent or more to consumers.

MR. : Okay. Thank you.

MR. : I'm Greg Bergt with Pennfield Animal Health, and I have a question on registration for U.S. agents on foreign firms. The certification statement in the form, does that need to be filled out by the foreign company to certify the U.S. agent?

MR. : No, the U.S. agent would identify -- if you looked at the form -- and I don't believe we have a form printed out, but it basically says if you are registering, whoever is registering, either electronically or by paper, would state that you are authorized and you would identify the person who authorized you in the registration form. So the owner, operator, or agent in charge, or someone from that facility's name needs

to be put into that block that authorized you on their behalf to do so.

MR. : On the certification statement?

MR. : There is a separate place for the name. There's a line there that would ask you to put in the name of that person.

MR. : Thank you.

MS. : Good morning. My name is Sujuan Shih. Our company is a frozen shrimp importer, and in our facility, we don't store any food. We store all the product in a public warehouse. Do we have to register for that?

MR. : Again, only the owner, operator, or agent in charge of that warehouse is required to register if they have food stored in there that is for U.S. consumption. So we would ask you to notify the owner, operator, agent in charge of that warehouse to do so. You do not have to register.

MS. : Okay. Thank you.

MR. : Good morning. My name is Taofiq. She sort of asked a question I better ask you. We have registered, but I still need to clarify certain

issues. We import from Africa. We don't own warehouse, not yet. Maybe we eventually might get a warehouse of our own. Do we need to -- we've registered. Do we still need to register if we use a public facility?

MR. : Okay. The only affected parties who need to register are those who manufacture, process, pack, or hold food, and who own, operate, or are the agent in charge of facilities who do so. If you do not produce food in a facility and own that facility, then you need not register. If you are an importer of food, this is not a registration of importers. This is a registration of food facilities. So if you do not own the warehouse, you are not required to register. It is the warehouse that we want to be registered, not the importer, not the broker, not the food itself.

MR. : So in essence if say two or three months down the road, we decide to get our own warehouse facility, what would happen? Should we cancel the registration we've got right now or we should leave it?

MR. : Okay. Again, you have registered, as I understand your question, you have registered your firm. We are not asking you to register

your firm. We are only asking you to register a facility, so in two or three months if you were to own a warehouse, at that time we would ask you to register that facility.

So, by and large, it seems to me that you have registered an entity that we have not required you to register.

MR. : Okay.

MR. : Should he cancel it?

MR. : It would be nice to cancel it because, you know, garbage in, garbage out. But again, we are not requiring firms to register. We are requiring facilities to register.

MR. : So I just have to make sure that the facilities we're using --

MR. : Yes, it would be good for you to notify them that they are required to register. You may do so on their behalf if they so authorize you. Just as the gentleman before said, where do I find that on the form, you can be authorized on behalf of the owner of that warehouse to register that facility for them, and just simply notify us of that fact.

MR. : So I will cancel my
registration. Thank you.

MR. : Okay.

MR. : Fred Schultz, Satellite
Logistics, Houston. We have a -- well, we have a 3PL that
only transloads merchandise. It doesn't sit in the
facility. Is it required to register? It is foodstuffs.

MR. : I do not know what a 3PL means,
I'm sorry.

MR. : A third-party logistics
warehouse.

MR. : Okay. Do you own that
facility?

MR. : WWe do not own it.

MR. : Okay.

MR. : But are they required to
register?

MR. : The answer, the owner of that
warehouse is required to register. There is no time
requirement for the packing or holding of food, so if food
is packed or held, unloaded, transferred, that facility is
asked -- is required to register.

MR. : Okay. And I don't know if I'm jumping the gun, what information are warehouses required to submit?

MR. : Okay, the information is the same as what I have shown you. The name, address, phone number of that facility, the name, address, and phone number of the agent, owner, operator, agent in charge. All of that information.

MR. : But there is no daily information of receipt --

MR. : None. No. This is a registration of food facility. It is not -- other than the product category of which that facility manufactures, processes, packs, or holds, that is -- we are asking for the general food category. So if it's alcoholic beverages, if it's grains, if it's animal feeds, whatever. And in the case of a warehouse, many times they would check most or all because they handle a variety of foods, and rather than trying to determine which ones are there now or in the future, it's in their best interest just to check most or all.

MR. : So the only thing that we have to do is register as a facility, if we own the warehouse?

MR. : Correct.

MR. : Is register as a facility, and then we are finished?

MR. : That is correct.

MR. : Thank you.

MR. : Paul Akhavan from Allied International. Regarding some of the questions that were being asked earlier regarding if you have to register your office or not, we were told even if you just hold samples in order to send to other people, then your office is technically a food-holding place, and I'm sure every office usually does hold samples from their products. Is that correct, that if you are just sending samples --

MR. : Well, I wish you hadn't asked the question because, truthfully, the answer is the intent of the act and the intent of these rules is to look at commercial facilities that do this. Obviously everyone in the course of their business, you or I at FDA, we have commissaries. We pack or hold food there, too. But we are not looking for those entities to be registered. We've

categorized -- and if you look at the rule, we said there's 420,000 food facilities worldwide. We're looking at major warehouses, we're not looking at -- and if we were to have counted all of the offices and associations that might hold food as a simple one-day activity, then it would be far in excess of 420,000. So that is not the real intent of this rule.

MR. : But if you have a sample room and regularly send and --

MR. : I didn't want to say no because that wouldn't be right, but you keep asking the question.

MR. : I have a question about retail. If there is a small store that is manufacturing carbon dioxide for use and selling it to beer consumers who are making beer in their homes, does that have to register?

MR. : The answer is yes. If it is a food-grade material, food additive such as carbon dioxide used in the production of food, and they are not -- well, if they are selling it as a retailer, then they may be exempt. If they are selling carbon dioxide from business to business, then they are not exempt. So they do fall under the definition of food, but they may be exempt

because they are a retailer. And again they would have to determine whether their sales are greater than 50 percent on an annual or fiscal year basis to consumers. If it is, then they need not register.

MR. : Okay. Thank you.

MR. : Good morning. Paul Rodriguez with the ARI. My question regards the definition of food products, regarding pharmaceutical placebos. Would you define that as --

MR. : Those are not food.

MR. : Not food?

MR. : Not food. This is a drug.

MR. : Okay. Well, the question came with my clients because the placebos are usually sugar pills.

MR. : Did you not like my first answer? [Laughter.]

MR. : Perfect. Thank you very much.

MR. : On the 50 percent calculation, if you have a mixed facility which sells foods and nonfoods, would you calculate the 50 percent on the --

MR. : No, the 50 percent rule only applies to retailers. If you have a mixed type facility and any product in that facility is covered by this rule, then that facility must register. Unless -- I mean --

MR. : So we have a retail business which is 99 percent retail directly to the consumer, but it contains both food and nonfood products.

MR. : Now, remember, this is a multi-criteria definition. You asked me about food, and I said the 50 percent rule does not apply to the definition of food, but it does apply to the definition of retail. So even though you may qualify under food, you may be exempt because you are a retailer. Okay?

MR. : Good morning. My name is Steve Bem. I'm with CJ International. We're a Customs broker here in the port. I just wanted to follow up on one of the questions about the cargo-handling process and the exemption thereof. It seemed to be that you stated that if a facility -- excuse me, if a warehouse transloads product, that they are required to register? They are not doing anything except moving product through in the course of normal transaction.

MR. : The answer is yes, and that is the current interpretation. We have met with many carriers, express couriers, world shippers, rail, trucks, and the interpretation that FDA has today, although you may submit a comment to the dockets if you so desire, is that we're -- while the transaction vehicles in and of themselves in the normal course of business from point A to point B is exempt, the terminal yard or the marine terminal or the rail yard is considered a storage facility or holding facility.

MR. : That's exactly what I was getting at.

MR. : And so we are saying under this interpretation that that yard is covered by this rule, and that should be registered.

MR. : A trucking company pulls a container, holds it in their yard overnight for delivery the next day.

MR. : Right. That's what we were saying.

MR. : Okay. Thank you.

MR. : Giovanni Degiorgis, Piedmont Imports (phon.). Question about USA agent for foreign facilities. In case of a communication to the facility, you would call the agent, and if there is a need of like going back to the FDA from the facility, would the agent carry the communication or would give the phone of the responsible facility?

MR. : Again, what we see as the role and responsibility of the agent is to be the first link between FDA and that facility. We could -- so generally speaking, we would expect communications to come back through that agent. However, there are certainly situations in which the food facility might want to communicate directly with FDA, depending on the situation. So it isn't required that all communications be solely through that U.S. agent, but we wanted an emergency contact so that we can reach that facility and that's what that role and responsibility is of the U.S. agent.

But, for example, if we have specific information that pertains to that food facility or food that they manufacture or process and there is follow-on investigations, then there likely will be ongoing

communications between FDA and that facility that may not go through the U.S. agent. They may be directly with other people at that facility, R&D, regulatory affairs people, and others. So I hope that answers your question.

MR. : Yeah, but so you mean that FDA, they can call directly the facility whenever they want?

MR. : Well, this rule doesn't obviate anyone from having communications over and above the purpose of this rule. What it is saying is FDA, as a general rule, if we have emergency information or routine communications with a foreign facility, we will first use the U.S. agent as that mode of communication.

MR. : All right. Thanks.

MS. : Good morning. Alexis Ellicott from the American Seed Trade Association. I have a question concerning the definition of farm. I understand that if you grow and consume on your farm that you would be exempt, but most large-scale farms grow things to sell off of the farm, so are they still exempt?

MR. : Yes. If you do traditional farming activities, you are exempt as a farm.

MS. : Okay, even if you sell what you grow?

MR. : Absolutely.

MS. : Okay.

MR. : I mean the definition of farm recognizes that the products produced there are shipped somewhere for being sold.

MS. : Okay. All right. Thanks.

MR. : Good morning. My name is Trung Trinh with Vietnam Resource Group, and my question is, what happened after December 12, a foreign company cannot register on time? So what happened then?

MR. : As I mentioned in one of my slides, FDA and Customs and Border Protection, depending on whether it's a domestic or a foreign facility, we are going to focus on and foremost on educating and trying to get facilities to comply. But at some point in the future, a failure to comply with the registration facility is a prohibitive act and FDA may take civil or criminal action against the owner, operator, or agent in charge of that facility, and also if it is a foreign facility, we may refuse importation of that food product into the U.S.

MR. : Thank you.

MR. : Good morning. My name is U.K. Nambiar. We import food products from India and the way we work, we have an exporter who goes to the open market and picks up about 20, 30 products, stuffs it in a container and sends it over here. Usually they store it in a facility over there, they warehouse before they ship it out. Now are all these 20, 30 manufacturers from whom they purchase these products required to register, or just the exporter?

MR. : The answer is the exporter is not required to register. It is a facility that must register. So in the scenario that you have outlined, it would be the manufacturer, processors of those 20 or 30 products would be required to register, as well as the last warehouse or shipper would be required to register.

MR. : The exporter actually warehouses it, so --

MR. : Well, then, if the exporter is the owner of that warehouse, then yes. But as an exporter per se, it is not required to register. Only the owner, operator, agent in charge of that warehouse.

MR. : Thank you.

MR. : That was an easy one.

Okay, I'm going to move on to prior notice -- oh, do you have another question? Okay.

MR. : My name is Taofiq again. He just drew my attention to some. If there is a facility in Africa that processing the food and you as the importer in the USA, are you compelled to register for and on behalf since you the sole importer and distributor? Are you then required to register for and on behalf of that company in Africa?

MR. : The company in Africa is required to register its manufacturing or processing facility. They may authorize you as their importer to do so on their behalf. So you may do so on their behalf, but you have to be authorized by them to do so.

MR. : Okay. Okay. So we -- of course we have communicated with them, so it means that we have to register their facilities on their behalf here?

MR. : If they authorize you to register, then yes, you must register their facility with FDA.

MR. : Okay. All right. Thank you.

MR. : All right, we are going to take
a 15-minute break.

[Recess.]

MR. : Please state your name and your
affiliation, and if you wish to direct a question to a
specific individual, you may do so. Otherwise, we'll
figure who's got the low end of the straw. Okay?

MR. : Elliot Kleinman, Citrus &
Allied Manufacturers of Flavor and Raw Materials.
Unfortunately I have a couple of questions.

According to some brokers, they need the PN
number before they can obtain the CBP entry number. Now
we're thinking we need the CBP number before we can get the
entry number.

MR. : There is no requirement either
way. You can file the entry with your prior notice, or you
can file the prior notice without an entry being filed.

MR. : How does that number get to the
shipment, mechanically? Like we get the --

MR. : To the shipper or to the
broker?

MR. : Well, we need a PN number in order to bring in this shipment. Now how do you know there's a PN number? Is this thing electronically transmitted to some piece of document, or do we have to notify the shipper of this number?

MS. : Can you identify what kind of an organization you're with?

MR. : Flavor and fragrance company.

MS. : So you're an importer?

MR. : Yes.

MR. : It is done electronically. If you use our ABI system, you're filing an entry as well as the prior notice information. So it will link up with the entry and it will be processed once the prior notice is satisfied.

If you are not filing an entry and you are just using the ACS, it will be linked up based on the identifier number which would probably be related back to the airway bill or master airway bill or whatever else you submitted at the time you filed your documentation.

MR. : So that's done internally in your group. We need to do nothing other than do the PN number?

MR. : Correct.

MR. : Okay.

MS. : Let me clarify something. If you have got -- you have a filer, correct?

MR. : I'm sorry?

MS. : You have a broker, a filer?

MR. : Yes.

MS. : They are going to transmit your data. Once FDA receives that data, we are going to transmit a status of PN received back to Customs to the filer with the PN confirmation number. Your filer should provide you with those numbers.

MR. : We may want to do the PN numbers ourselves.

MS. : You may want to go through our Web.

MR. : In other words, the prior notice number -- I don't know that I want to give the

broker all this -- give the responsibility to the broker.
I don't want to put them in a different business.

MR. : That's a decision you're going to have to make on your own. That's a business decision. How you submit the documentation for your prior notice, whether you go through ABI or ACS or through the FDA Web site, based on how it's filed, whoever files it will get back the response from FDA. So your answer -- the answer to your question is depending on how you file it, whoever files it is the one who's going to get the response, and if the person filing it is not you, and you want to get an answer, then you're going to have to work out a business deal with whoever it is that's submitting it for you to notify you that they have received it.

MR. : But where does the number -- where does that number go? That's my question. Because if you are asking me to do this through a broker, there's going to be a charge, and if I'm doing 500 shipments a month, that could be a big expense. My shipments average between 500 and 750 shipments a month.

MS. : If you are using a filer they will understand that a lot of the PN data elements are data elements that are already being transmitted.

MR. : Okay.

MS. : While there are additional elements, there aren't that many more. So what's going to happen is if you don't choose to transmit them -- and again, as Howie says, it's your business decision, but if you choose to have your filer transmit the entry and submit your own prior notice information, you're going to be submitting the same information twice. And that's why we worked with CBP to get this interface to allow the prior notice data because people didn't want to have to transmit data twice.

MR. : And one final question that seems to be irking at least my industry. The registration number that we receive when we register, it was my impression through another outreach program that this registration number is kind of sacred to us. It can't be obtained by the Freedom of Information Act, but yet everybody in the industry is exchanging registration numbers for proof that they are registered. What do you do

with the -- what is the registration number exactly? In other words, if I want to protect the food supply, I would think -- now maybe I'm wrong -- that the registration number should be held private to me. What could be done with the registration number? Because I've got to tell you, the entire industry has submitted it to each other. I've got a thousand of them.

MS. : But that's a business decision. What we say is that we won't provide that number to anyone. If you choose to provide it to someone else, there's no problem. What we use the registration number for in prior notice is to match the manufacturer information that's transmitted, to see that that -- the registration number matches the name and address that's submitted as the manufacturer.

MR. : Okay. Now if that is true, we're protecting against an unknown enemy, I would suggest, so if those registration numbers are submitted for me to every company I do business with, and every customer I do business with, I have their number, what's to prevent this unknown enemy from obtaining registration numbers?

MR. : Okay, your point is the registration numbers, just as she has mentioned, Kelle has mentioned, FDA is under statutory language not to release that information. We recognize from a business standpoint so that goods can flow from one party to another, you may have to share that registration number with your next in line of the food-production-to-consumer chain. People are asking for confirmation that you have complied, and that is one way for you to share that.

If the registration number is shared, people who receive that number do not know all the information that's behind that. They do not all know the required information that you have already provided, the address, the phone number, the fax number, and all of that. So if someone were to misuse your registration number, when we get that registration number for a food product and it does not coincide with the information we have in the registration database, that will flag it as being something untoward, and we will follow up on that.

So we recognize that businesses are going to share prior notice -- I mean are going to share

registration numbers, but again the only prohibition is on the government not to share it.

MR. : Now -- and I don't want to belabor this, but I got to think that what you just explained doesn't help me. Is there a PIN number that coincides with the registration number?

MR. : Yes, there is.

MR. : Okay, so that's the answer to the question then. In other words, you need the registration number and a PIN number?

MR. : To go in and change any information or to view that information.

MR. : Right. And some company trying to --

MR. : Would not be able to access it without the PIN number and the registration number.

MR. : Right, so you need both. So the registration number has really no significance?

MR. : Well, I didn't go that far, but yes.

MR. : Okay. Thank you.

MS. : But when you're giving prior notice, can somebody use your registration number to give prior notice, or does it require you to give the PIN number, too?

MR. : As you saw in the field, the required information, only the registration number is required. The PIN number is your secure way of accessing the information you have submitted under registration.

MS. : So, in other words, somebody could go in, if they wanted to give prior notice to a shipment coming in, they could use your registration

number? MR. : But unless it coincided with the exact type of commodity produced in your facility, then it would not work, because we are going to be reviewing that information.

MS. : But I don't produce -- I'm an importer, so there are some companies like -- I have brokers for some of my imports, but there -- like I have a private label, Sun of Italy, and I import tomatoes under this label, I import olive oil, olives, from all different countries. So on some of these items I deal directly with the country, and even on like lemonades and stuff like that

of other brands, I deal directly with the country. I was -
- when I registered, I called FDA because Canada called me
and said we cannot ship this shipment to you until we have
your registration number.

So I called FDA, the help line, and they says, no
way, you know, you have to have their registration number
to make sure they're registered.

MR. : That is correct.

MS. : So that's what we've been
doing, sending out a letter to like all our foreign
companies that we have to have their registration number to
know that they applied.

MR. : That's correct.

MS. : But now how will I know they
gave prior notice for this product to come into the
country?

MS. : Typically the person that's
going to provide prior notice like it is -- normally it's
going to be same entity that's filing an entry with Customs
now.

MS. : Okay.

MS. : So, you know, as Lou explained, we didn't limit who could give us PN, but we expect that most people are going to follow regular business practices.

MS. : So it will be just like I've been doing.

MS. : Right. You're going to contract with a filer, you are going to get all -- you or they are going to get all of the required information to transmit to us.

MS. : Okay. Okay. That's what I was worried about. And so then that will be good.

But you said perishable items, if they're not acceptable, will be destroyed in three days, carrier responsible, and then they got to work out the payment with the shipper. Some things that you buy from foreign countries, they do a draft out of your bank account before you -- before they even ship. So then that means me as the importer would be stuck?

MR. : That's no change from the current procedures in place for merchandise that ends up in GO. If a shipment comes in and it's refused or has to go into GO for any particular reason and it's perishable, it's

three days public notice and then the goods are either destroyed or sold.

MS. : Well, with this prior notice thing, I ship mostly by boat. So and that's like less than eight hours. That gives me like -- almost half my day is gone then.

MR. : Well, what do you bring in?

MS. : I bring in perishable. From France I bring in fruits, frozen fruits.

MR. : But aren't they refrigerated or properly --

MS. : Frozen.

MR. : Okay, so they're frozen. They are in freezers?

MS. : Yes.

MR. : So you're not taking them out of the freezers. They're not going to sit there melting on the pier?

MS. : No, but you said after three days you'll destroy them if --

MR. : If it's a perishable good that's rotting on the piers, we're going to destroy it.

MS. : Oh, okay.

MR. : We're not going to -- if you've got a proper facility for keeping it, you know, refrigerated or frozen or whatever else you need to do, we're not going to destroy it.

MS. : Oh, okay. That's what I was wondering. Thank you.

MS. : Maryann Pastore.

MR. : Nancy Sharp, Select Wines. I had a question regarding samples coming in either air shipments or by boat, typically. With our broker, we had just filed -- they were samples, and what type of wine they were, still wine, sparkling wine, et cetera, for duties' purposes. They are not for resale. With this new prior notice, are we going to have to itemize all of the samples? Yes? Okay.

But it doesn't need ATF approvals?

MR. : No other laws or rules are changes.

MS. : Okay.

MR. : I mean if they were subject to ATF prior --

MS. : They weren't before, so --

MR. : Then that doesn't change.

MS. : You just have to itemize them,
now; correct?

MR. : Yeah.

MS. : Yes. And then I'm assuming, or
I was trying to figure out if a foreign facility had
registered or not, there isn't an FDA on the Web site. Is
there a list of registrations that you can check? No? You
have to check that individually with each business?

MS. : Correct.

MR. : Again, FDA is not allowed to
identify who is registered and that information. You need
to have a business relationship with whoever you receive
your wines from to get that information.

MS. : Okay. Thanks.

MR. : My name is Taofiq, representing
Africa, Incorporated. If I'm bringing in say five
different products from Africa, am I supposed to bring --
send samples in advance before the ship is loaded? Am I
supposed to send samples to make sure that confirm with
whatever requirement you asking of me?

MR. : There is no requirement that you ship samples prior to your shipment. Some industries send as a manner -- part of their business of either new products, new lines, new vintages, new whatever. So they do that as a matter of business always. So you are not required to send samples, you simply send your shipments.

MR. : So in essence if I load the container, I get the prior notice from you maybe two weeks before the container is loaded from my home country --

MR. : No. Again, remember, the time element is no earlier than five days, and if it comes by boat, no less than eight hours. So prior notice must be submitted within that timeframe.

MR. : So in essence even if I bring in the goods that I get a prior notice, that does not give me a guarantee that when the good come, you will -- if you decide to destroy, whatever, you can simply destroy?

MR. : Again, we are talking here about prior notice. If you have complied fully with prior notice and any other registrations that apply to your products, then your products will go into commerce as they normally do.

Failure to comply in prior notice then would start a series of actions until you did fully comply with prior notice.

MR. : All right. Thank you.

MS. : Can I just say, it's no different than what you go through now. You've got products on a ship, they come in. There's no guarantee that they are going to pass our 801(a) screening. They can still be detained and refused entry. So from that standpoint, things haven't changed.

MR. : Jay Ansell, Yves Roche. I have a question concerning packages going by international mail. We have a warehouse in Canada and ship to consumers via Canadian post. We are now required to provide the prenotification -- prior notification because we put the package in the mail?

MR. : Yes.

MR. : We will then get a refusal if -
- I mean when would the refusal come?

MR. : If there's -- well, it would be a prior notice satisfied, not just that you applied for it.

MR. : Right.

MR. : So if you had a satisfaction on your prior notice, you wouldn't get a refusal. You would only get a refusal if there is no prior notice.

MR. : And that would happen immediately?

MR. : At the time it came into the U.S.

MR. : If you submit prior notice electronically and you have satisfied all of the data elements within that prior notice, you will electronically receive a prior notice confirmation number, which is an acceptance.

MR. : Good.

MR. : Now, as we have said, FDA will be doing an assessment of that information. We will be transferring that electronically to Customs and Border Protection or FDA at the port of arrival. You will then need to look at all of the other FDA registrations vis-a-vis that product. As Kelle has just pointed, 801(a) admissibility. But as far as prior notice submission, if you satisfy the submission, you will get a prior notice confirmation number back.

MR. : And I guess a question to Customs. Canada post is starting to implement -- starting to work on implementing registrations of their own. Is Customs working with them to try to clarify some of these issues?

MR. : I don't know. I mean we have people that work in our mail branch and deal with international mail, so if there is a joint effort going on, they would be the ones doing it. I'm unaware of any.

MR. : Thank you.

MR. : Giovanni Degiorgis, Piedmont Imports. Food animal embryos, are they considered live animals? So food?

MS. : You said food animal embryos?

MR. : Yes. Like bovine embryos, are they considered live animals, or food, so subject to prior notice?

MR. : I would suggest you check the harmonized tariff numbers when they are posted and see where they are classified, and if they are classified under one of the items that require prior notice, then the answer

is yes; and if they are not listed as an item that's subject to it, then the answer is no.

MS. : My guess, off the top of my head, is that embryos are considered a biologics product, regulated by our Center for Biologics. But Howie makes a good suggestion, that the decisions on whether something is regulated under prior notice is all tied to the tariff code and the FDA indicator that's been -- the new FDA indicator that's been linked to those.

MR. : Okay. Thanks.

MR. : Any other questions? You don't have to.

[Laughter.]

MR. : Bill Fenton with TAG, USA (phon.). Just a question. If you file prior notice through ABI ACS and/or FDA PN, will it send you to the same document, same format? If you pull up that Web, you get a document you've got to fill out, like a PN document?

MR. : The answer is no.

MR. : They will be different?

MR. : Right. ABI ACS is -- they are basically modifying the current system they have to add the

additional data elements. The FDA system is de novo. We're creating a brand new system that didn't exist before. So they will have the exact -- you will be entering the exact same information, but they may not look exactly the same because, as we have tried to say, if you are currently using ABI ACS, you will be able to continue to use that and it's being modified so it can take in --

MR. : Adding some more data you needed?

MR. : Right.

MR. : While we are waiting for the next question, I just wanted to point out two things. Even though you have a five-day window to file prior notice, that window will not be open until December 12th. So any goods coming five days prior to December 12th, you will have to wait until December 12th to file the prior notice because it will not be available for submission.

The other thing I wanted to point out is that on December 12th, unless we actually have what we have determined to be an actual hazard, an actual biological hazard, no shipments are going to be held and stopped for paperwork errors or lack thereof. So initially during the

informed compliance period, the timeframes are being discussed between the two agencies, but initially no shipments are going to be held on December 12th, unless there is an actual threat.

MR. : What do you anticipate the learning curve to be?

MR. : That is under discussion between that agencies.

MR. : Right. As I mentioned, we will be publishing an enforcement discretion document jointly between FDA and Customs. We will stipulate in there what that learning curve period of time is. We are not at liberty to say right now, but it will be more than -- well, it will be several months, for sure.

MR. : Yes?

MS. : Nancy Sharp, Select Wines, again. More sample questions. If you send samples regular post, who would be submitting the prior notice? Me, as being the recipient, or the person shipping the samples?

MR. : It has to be on the package, so whoever is sending it would have to --

MS. : Like say if FedEx did it or whatever, are they doing it?

MR. : If you are sending it by mail, when you mail it, you would have to have it on the Customs form. If you are doing it by courier, then, you know, again, that's a business arrangement. Either your shipper or you or whoever you choose --

MS. : Well, sometimes I don't know they're coming. They're just shipping them, so that's why I'm saying do I have to notify people when they ship me samples, I have to know in advance now --

MR. : Yes.

MS. : -- because they didn't give me notice before, they would just ship them.

MR. : Well, they have to at the very least give you prior -- have prior notice met.

MS. : So then appropriate paperwork can be submitted either through FedEx or --

MR. : Correct.

MS. : -- the mail service? Or whatever, correct?

MS. : Or you can file it.

MS. : Or I can file it. And if it's overnight, then it means you basically might be submitting it after it's arrived?

MS. : Well, which means it's subject to hold.

MR. : Which means it will be held.

MS. : Okay. All right. Thank you.

MR. : And it will be subject to refusal.

MS. : Okay.

MS. : Good morning. Elda Devarie from EMD Sales. We import ethnic products from different countries. Once it's -- once the paperwork is done and we get -- the confirmation arrives to my broker, then they are responsible for sending it to the shipping company that is going to bring the products to us?

MR. : That's a business decision between you, your broker, and your shipping company.

MS. : But the document has to be over at the trucking company or railroad company so some kind of electronic transmission needs to happen, so definitely the

broker will be -- will have to be responsible for something like that?

MR. : Yeah, whoever is filing your paperwork.

MS. : Whoever is filing the paperwork. Okay.

MR. : Hi. My name is Trung Trinh with Vietnam Resource Group, and one of my job is to coordinate trade delegation from the other country coming here. My question is, I just want to clarify to make sure that I understood clearly about the prior notice. If some other member, they bringing with them some food sample, do they -- I mean is it required to be sending the prior notice?

MR. : If it's a food sample, yes; if it's for personal use, no.

MR. : Okay. And they can do it at the -- they have to do it in advance before they arrive at the airport?

MR. : Right. They have to meet the timeframes.

MR. : Thank you.

MR. : Butch Connor with John S. Connor. In reference to consolidated containers, if it were to be determined that there were say one or two lots in a consolidation which did not receive prior notice, how is that going to be handled in reference to holding the container and whether the container will be stripped at destination port before the goods can be moved, or the remaining goods can move that are not part of the public --

MR. : Are you talking about an IT?

MR. : Well, not necessarily -- well, that's what I'm trying to determine. If the container -- let's say it's a consolidated box. It comes to LA, but it's fully routed to New York, but the determination was that there were some products in there that did not get prior notification, will it hold the full container in LA?

MR. : Yes, until it was segregated.

MR. : Okay. And so it will be pulled to a CFS?

MR. : Whatever the procedure would be at the port, yes.

MR. : Okay. And then the remaining goods, once those are stripped out, the container would move?

MR. : They will be allowed to move the balance of the goods.

MR. : Okay. Thank you.

MR. : Paul Rodriguez, ARI. One quick question. I just want to make sure that I fully understand this. It seems like a lot of importers, food importers, are registering their companies, and what I want to make clear here so I can fully understand it, is that unless they have a warehouse and they are actually the recipient and the holder of the food product, at that point it's required for them to register. But if they are not the actual recipient or have a warehouse where they're holding the product, it's really not necessary for them to register.

MR. : That is correct.

MR. : Okay.

MR. : Again, it is registration of food facilities only, not an importer, not a firm, not a company. Only the facility.

MR. : Bill Fenton, again. And again I ran this by the young lady earlier. I'm acting as the U.S. agent for a company that we have and the question I have is on PN notices, the U.S. agent need not be notified of any prior shipments; is that correct?

MR. : That is correct. Again, the U.S. agent --

MR. : If you have a problem with a shipment, the first person you are going to call is the U.S. agent? He's your local contact?

MR. : No, remember in the slide at least that I offered, there is -- we are requiring in a prior notice the owner, consignee of that product, and if -- in an import, and our normal course of business with a refused shipment would be to notify one of those to remedy the situation, not the U.S. agent.

Again, the U.S. agent refers to a food facility. It may not be the person shipping that product. As we have heard from many other people, they are consolidating many different manufactured products into a shipment. So they are not the actual manufacturer, they are simply a consolidator. So we are going to be looking to the owner-

consignee or importer here, and contacting them if there is a refused product.

The U.S. agent most notably would be contacted if we have information about a shipment, information about a food product, information about a type of facility that we need to convey to a foreign facility, and that's when we would notify the U.S. agent.

MR. : So, in reality, the U.S. agent only needs information on the facility that's doing the shipping?

MR. : That is correct.

MR. : He doesn't need to know about any of the shipments themselves?

MR. : That is correct.

MR. : Okay.

MS. : If you look through all the documents on prior notice, you won't find any reference to U.S. agent. That is a requirement of registration only.

MR. : Hi, Maryann Pastore. He was saying before about the prior notice, about the broker. Now brokers, they are not a food facility. They don't

contain the food in their facility, but shouldn't they register in order to be able to give prior notice?

MR. : The answer is no.

MS. : No. Okay.

MR. : Registration applies only to food facilities. We are not registering firms, we are not registering brokers, we are not registering importers. We are registering food facilities. Again, in the rule we say we believe there are an estimated 420,000 food facilities that manufacture, process, pack, or hold. As an importer, you may do none of those. You need not register. Only if you do those things in a food facility must you register.

MS. : Okay.

MS. : I don't know if it makes it any easier. Lou has said it, but maybe looking at this way, that registration is, as he said, for the facility and prior notice is for the product. If that helps.

MR. : Franco Faggi from Terminal Imports, and I'm dealing with wine and liquors. And earlier you had referred to apparently on the previous notice, who would be the ultimate consignee. In a case that being the importer, at time we ship product to a

distributor in other states. Who is considered to be the ultimate consignee? Would we be the ultimate consignee since we are actually the one taking delivery of the goods in the U.S.? Or the wholesaler, the distributor in another state?

MS. : The requirement for ultimate consignee hasn't changed. It's the Customs definition, and it is the consignee known at time the product is shipped.

MR. : Okay. All right. So nothing is going to be changing on that matter?

MR. : Yes.

MS. : I mean, you know, we know that you might declare someone as the ultimate consignee and there may be some sales made after that point.

MR. : Correct.

MS. : But we need to know who the ultimate consignee is at the time the product --

MR. : Of entry?

MS. : Right.

MR. : Correct. Thanks. Thank you.

MR. : Any other questions? There was a question during the break. I want to reemphasize that

the slides that we have used today are on our FDA Web site. Again, if you don't have access and you would like us to send you a copy, please give me your card before you leave, and we will ship you off a copy or electronically send you a copy of those slides, if you so wish. I know you were rapidly copying those numbers, but we can actually send it to you if you like.

MS. : I'm sorry, I do have a question. I think I can speak up without the microphone.

MS. : You have to get it on the recorder.

MR. : You can go around the front.

MR. : You can come around the front.

MS. : Hi. My name is Lisa Treut, and I am from the Port of Wilmington in Delaware. I just have this question in my mind, so forgive me. We have our registration number. We are a warehouse. We are a port and warehouse. I got that down. What do you expect of us, though, now that we have this number? When are we going to know what your expectations for us to do is, or is that all we are supposed to do, is just register?

MR. : That is all you are supposed to do is just register. What FDA -- this is the first time FDA will know where food facilities are located worldwide, and for our purposes, so that we can do a more effective and efficient job from a food safety and food security standpoint, is to know where food is both manufactured, processed, packed, or held.

There are other rules that we will be issuing later this year, such as records requirements, establishment and maintenance of records, as well as administrative detention.

If FDA determines, either through intelligence or known contamination of a product, that a product may pose serious adverse health consequence to the U.S. consumer, we will ask for a product to be held in that location. It may be your location. If we so find that to be the case.

We will then have to take legal action against that product while we hold it for a period of time at your location.

So -- or in other cases, where we are doing inspections, we will then obviously know where your place of business is. We can visit it and make sure you are

adhering to the rules and registrations that apply, and make better use of our time and your time in doing that.

So registration is really to give FDA better information than we have had before so we can do a more effective and efficient job.

MS. : Okay. So I guess my basic question is down the road this year we'll find out what the other expectations are for recordkeeping and things like that?

MR. : Correct.

MS. : Because I'm having a very hard time finding that on any of the FDA Web sites.

MR. : Okay. We published the proposed rules on establish and maintenance of records in May, as well as on administrative detention. We are expecting to finalize those rules either in December, January, or February of this year -- or this year or next. So they will be coming out in the next few months.

MS. : Okay. And just -- I'm sorry.

MR. : And again, as we proposed in the establishment of records, there was a phased-in timeframe. It's likely that that will be phased in by the

size of the company. And again, both of those rules are passive in the sense that we are asking firms to establish and maintain records, but you are not required to provide FDA those unless we come and ask those based on criteria that we have to meet.

So we are asking you to have those records in the event that we come and inspect and required you to produce those. We are not asking you to produce those on a regular basis to FDA.

MS. : Okay. And just one more clarification question. The way reading all this is that Customs will not release it unless all the prior notice has been made. So as a port, normally the agents for the vessel don't release the cargo until everything is satisfied. I just want to make sure that that's how it's going to happen.

MR. : Yes.

MS. : Okay. So I really don't have that much of a worry. That sounds good.

MS. : Hi. My name is Sujuan Shih. I'm with Aqua Beauty, Inc. We are importer. I have a question is do we have to ask all our packers to put their registration number on the documents?

MS. : It doesn't matter how they provide it to you, but if you are going to enter their product, you are going to have to supply their registration number.

MS. : For the prior notice?

MS. : Right.

MS. : Okay. Thank you.

MR. : Any other questions? Okay.

MR. : My name is John Perez, representing John A. Haas (phon.). We're a food processor, and the question is if we are importing goods and on the -- and we have to submit a registration number, in addition, do we enter the registration number of the food processor, let's say in the case -- it's in Germany, and do we also enter the registration number of the freight forwarder? We, for example, hire freight forwarders. They hold the goods at their facilities at a warehouse facility in Hamburg, Germany for a week. Will we submit both registration numbers or just the food processor's?

MS. : Are they the shipper?

MR. : The shipper would be the food processing facility in Munich, Germany.

MS. : Correct me if I'm wrong, but my understanding is that you have to have the registration number for the manufacturer and the shipper if they are required to register.

MR. : Okay. So when we submit the prior notice, we submit both registration numbers then?

MS. : Right, if the shipper is required. They may not be.

MR. : So there may be more than one?

MS. : Because the shipper may never hold the product.

MR. : Okay. Okay, thank you.

MR. : Again, are there any other questions?

Okay. Thank you very much.

[Whereupon, the conference was concluded.]

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